K020903

SEP 2 6 2002

DOCXS LLC
Bio Medical products
Ag-AgCl Electrodes
Vascular Occluders

510(k) Summary

Cutaneous Electrodes

Biopotential Electrodes,
various types

Date of Application: 3/15/02

Company name: DocXS, LLC
Address: 564 S. Dora, Unit A #1
Ukiah, CA 95482
Mailing Address: 12200 Pine Ave. Potter Valley, CA 95469
Phone: 707-743-1365
E-mail: DocXS@pacific.net
FDA Reg. #: Submitted application and waiting for response
Submitted by: Richard A. Rizzolo, Principle
Address: 12200 Pine Ave., Potter Valley, CA 95469
Phone: 707-743-1365

Signature:

Description of Device

Product Description: Biopotential Electrodes, various types and models
Proprietary Device name: B series electrodes
Common\Generic Name: Biopotential electrodes, various types and models
Trade Name: Cutaneous electrodes
FDA Classification Name: Cutaneous electrodes
Device Class: 2
Product Code: GXY
Regulation Number: 882.1320
Medical Specialty/Panel: NEUROLOGY
Manufacture of original device: NA
Establishment Operations: manufacturer

This specific device is comprised of a sintered Ag-AgCl electrode with a 99.99% Silver wire. Some of the electrodes are to be sold as bare electrodes. Some are set and sealed in an epoxy or silicone housing with a PVC, Silicone or other TPE insulated, tinseled copper lead wire attached. The device is then sealed with either silicone or Epoxy. They have a smooth, non-porous finish on all surfaces with no cracks, seams, or bubbles. It is then considered waterproof and cold sterilizable. There is a recess in the underside of the housing surrounding the exposed electrode surface to allow for the placement of an electroconductive gel. The gel establishes contact between the Ag-AgCl electrode and the subject surface to be measured. The gel improves electro conductivity between the subject surface and the Ag-AgCl electrode surface for a more sensitive and accurate reading of the Biopotential.

The lead wires are either unterminated or terminate with a 1.5 DIN safety socket, snap, or pinch connector. examples section 4, 5, 6

Labeling

Labeling: Package Label, see sample label below

- Instructions for use, Promotional material, Specific intended use statement, included with device, **example page...** Section 4 page 3 of 4
- Warnings, contradictions, or limitations: included with device, **example page...** Section 4 page 3 of 4

Sample Label:

Manufactured by **DocXS, LLC**
564 S. Dora, Ukiah, CA 95482 707-743-1365

Biopotential Surface Electrodes
Contents: One Ag-AgCl electrode, 8mm X 1mm in Epoxy
Model: B-224-LS, 40" red
Indicated for use in acquisition of surface biopotentials
Refer to instructions before use Batch #: **non-sterile**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 6 2002

Mr. Richard Rizzolo
DocXS, LLC
564 South Dora, Suite A-1
Ukiah, California 95482

Re: K020903
Trade/Device Name: DocXS B Series Electrodes
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: Class II
Product Code: GXY
Dated: August 13, 2002
Received: August 23, 2002

Dear Mr. Rizzolo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., MD
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020903

Device Name: Cutaneous electrode, Biopotential skin electrode

Indications for Use:

Biopotential skin electrodes will be used by the Bio Medical community in both clinical and research applications of the acquisition of all surface biopotentials, standards, and reference, i.e. Electroencephalograph (EEG), Electrocardiograph (ECG), Electromyography (EMG), Electrooculograph (EOG).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

(Optional Format 3-10-98)

510(k) Number K020903